REMARKS

Applicants' Attorney wishes to congratulate and thank Examiner Woolwine for his outstanding helpfulness in completing the allowable claims. This is reminiscent of the finest activities of the U.S. Patent Office when Examiners and Attorneys collaborate to efficiently define fair and allowable claims. Support for the Amendments can be found in the original claims.

For reference, pages 2 and following of the Office Action are set forth below, with Applicants' Remarks interspersed.

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DETAILED ACTION
Status
Applicant's response filed 04/06/2010 is acknowledged.
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Despite Applicant's amendments to the claims, issues remain with regard to 35 USC 112, 2nd paragraph. Some of the previous issues under this rejection have been corrected by the amendments to the claims, but other issues remain and some new issues have been created because of Applicant's amendment to claim 5. Any issues not discussed in the rejection below may be considered withdrawn as no longer applicable.
In addition, Applicant's attempt to amend the specification to delete nucleotide sequences, in order to comply with 37 CFR 1.821-1.825 is noted. However, as discussed in the previous Office action (page 5), figure 2 and paragraph [0059] also disclose a nucleotide sequence.
As discussed in MPEP 2422.02: "It should be noted, though, that when a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings."
Therefore, Applicant will have to submit a Sequence Listing in compliance with 37 CFR 1.821-1.825, as discussed in the previous Office action, or else amend the drawing (figure 2) and paragraph [0059] to remove the sequence. For example, Applicant may remove figure 2 and corresponding text from the specification altogether.
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or draw the secondary structure without the sequence and remove the sequence from paragraph [0059]: ....

Applicants have submitted the required Sequence Listing via EBC FS Web as helpfully suggesedt by Examiner Woolwine.

Claim Rejections - 35 USC § 112
The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
Claims 2-5, 11, 12 and 14-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is noted that all claims depend directly or indirectly on claim 5. The preamble for claim 5 clearly recites "A scalable process for ... the separation of a desired recombinant polymerase from undesired nucleic acid", but the body of the claim still recites "exposing purine bases present within either the desired nucleic acid product or
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undesired nucleic acid" (lines 4 and 5, emphasis provided). It is respectfully pointed out that there is no "desired nucleic acid" in this claim. Furthermore, Applicant's amendment at lines 9-11 ("capture of the desired recombinant polymerase by a technique selective for single-strandedness") does not make any sense. A recombinant polymerase does not comprise single-stranded nucleic acid (or any nucleic acid for that matter); a recombinant polymerase is a protein. It is respectfully pointed out that the embodiment for purifying polymerase as described in the specification is to capture the undesired nucleic acid (e.g. contaminating genomic DNA) on IMAC, separating the IMAC matrix with the bound nucleic acid from the sample, leaving behind the purified polymerase. The polymerase is not captured. Nor is it understood how one could capture a polymerase by a method selective for nucleic acid single-strandedness.
Because all claims depend ultimately from claim 5, they are rejected for the same reasons. Furthermore, the claim in its current form cannot be searched over the prior art because of the inconsistencies noted above. In order to assist the Applicant, the examiner has taken the liberty of drafting a set of claims drawn to the embodiment of purifying a polymerase, which Applicant may wish to consider. The examiner would normally have attempted to contact Applicant's representative and set up an examiner's amendment. However, since Applicant must also address the sequence compliance issue (figure 2), the suggested claims were
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included in this Office action. The suggested claims are (note numbering begins with "new" claim 26):

26. A method for separating a polymerase from nucleic acid in a sample comprising:
treating the sample to expose purine bases present in the nucleic acid by a process selected from the group consisting of thermal denaturation, alkaline denaturation and restriction enzyme digestion yielding single-stranded overhangs;
capturing the exposed purine bases of the nucleic acid on a metal chelate matrix, wherein the polymerase does not bind the metal chelate matrix;
separating the polymerase from the metal chelate matrix; and
recovering the polymerase, thereby separating the polymerase from the nucleic acid.

27. The method of claim 26 wherein the polymerase is a thermostable polymerase.

28. The method of claim 27 wherein the polymerase is Taq polymerase.

29. The method of claim 26 wherein the nucleic acid is genomic DNA.

30. The method of claim 26 wherein the sample is a cell lysate.

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31. The method of claim 26 wherein the separation is achieved using multi-channel plates.
32. The method of claim 26 wherein the separation is achieved using magnetic particles.

33. The method of claim 26 wherein multiple samples are treated in parallel fashion.
34. The method of claim 26 wherein the metal chelate matrix comprises Cu(II) .
35. The method of claim 26 wherein exposing is performed by thermal denaturation followed by quenching in a high salt buffer.
36. The method of claim 34 wherein the high salt buffer comprises 20 mM HEPES and 500 mM NaCl.
37. The method of claim 26 wherein exposing is performed by thermal denaturation followed by rapid cooling.

Should Applicant find these claims acceptable, Applicant should address the sequence compliance issue (figure 2), cancel claims 1-25, and submit the claims above as an after-final amendment, in which case the amendment will be entered.
The examiner would point out that Applicant's last amendment to claim 5 shifted the focus from methods "selective for exposed purine bases" (of which Applicant has only disclosed one, i.e. IMAC) to methods "selective for single-strandedness". If Applicant

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wishes to pursue this broader aspect, and submits an after-final amendment
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Applicants adopt the claims exactly as helpfully suggested by the Examiner and will appreciate Examiner Woolwine's entry of them..

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correcting the deficiency under 35 USC 112, 2nd paragraph discussed above, such that the claim could then be searched over the prior art, such an amendment would not be entered as it would require further search and consideration (for methods based on capture techniques selective for single-strandedness).

Without prejudice, Applicants do not elect selective for single strandedness at this time.

Conclusion
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any
extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.
Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAMUEL C. WOOLWINE whose telephone number is (571)272-1144. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.
For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.
/Samuel Woolwine/

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Primary Examiner, AU 1637

This response is filed within two months after the Final Rejection mailed 7 July 2010 and an advisory action or Allowance is earnestly solicited.

The Amendments are for clarity and are not required to distinguish from the references as there are no remaining rejections on Prior Art. No new matter or estoppel is involved.

Any necessary fees (small entity) may be charged to Deposit Account 200336 of Technology Licensing Co. LLC.

The Examiner is especially invited to telephone Applicants' Attorney if that would expedite Allowance of this Application.

Respectfully submitted,

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